



Wholesale Dealers of Fresh Seafood & Live Lobsters  
www.lobstertrap.com

January 21, 2005

Dockets Management Branch (HFA-305)  
Attn: Docket No. 2004D-0510  
Food and Drug Administration  
5630 Fisher Lane  
Room 1061  
Rockville, MD 20852

RE: COMMENTS ON DRAFT GUIDANCE ENTITLED "PROPOSED REFERRAL PROGRAM FROM THE FOOD AND DRUG ADMINISTRATION TO THE NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION SEAFOOD INSPECTION PROGRAM FOR THE CERTIFICATION OF LIVE AND PERISHABLE FISH AND FISHERY PRODUCTS FOR EXPORT TO THE EUROPEAN UNION AND THE EUROPEAN FREE TRADE ASSOCIATION"  
(Docket No. 2004D-0510)

To Sir or Madam:

Lobster Trap Co. is one of the largest exporters of live lobsters in the country and we have been shipping live lobster to the European Union since 1993. I am writing to let you know of our opposition to the proposed twenty-four month referral program. This new program would effectively put an end to a large portion of our business due to the fact that health certificates would no longer be able to be ordered in advance.

In the lobster business, things change by the hour and our call in business could not possibly be accommodated unless we had the health certificates in house as we do now.

The FDA inspects us, we run an FDA accepted and appointed HACCP program, we are on the EU accepted shipper's list and have a CFN (Central File Number). We type in the information on the blank certificates and send them to the FDA prepaid. The FDA, in turn, stamps a certain number of the certificates and sends them back prepaid by us.

If we are not able to make a move at a moments notice, as the current system allows us to do now, it would be crippling to say the least and hundreds of thousands of export dollars would be lost.

2004D-0510

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We have used the Dept. of Commerce in the past but lagged behind and lost business to Canadian competitors (I have heard that Canadian exporters do not pay for their certificates) due in part to the high cost of the DOC program which ran anywhere from \$50.00 per hour to \$200.00 per hour depending on time of day or holidays. When the FDA program was born, we immediately switched over and saw our export business bloom.

If money is an issue, (it's an issue for all of us) we would support the FDA imposing a fee for the health certificates even though it will STILL be OUR staff filling in the information on the certificates! Based on our usage of health certificates in 2004, a fee of \$10-\$25.00 would raise, roughly, \$10,000 for the FDA's resource problem.

I'm confident that this will be an industry wide problem and, if this program is put through, will cost us, as an industry, millions in export dollars!

All the best,



David Madden  
European Sales Coordinator